UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

JOHN BARTOLI,	:	
Plaintiff	:	**CIVIL ACTION NO. 3:13-0724**
v.	:	
		(JUDGE MANNION)
NOVARTIS PHARMACEUTICALS CORPORATION,	:	
	:	
Defendant	:	

M E M O R A N D U M

Pending before the court are defendant Novartis Pharmaceuticals Corporation's ("NPC") motions, brought pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) and Federal Rule of Evidence 702, to exclude the expert testimony of Dr. Keith Stubitz, (Doc. 183), Dr. Robert Marx, (Doc. 185), Dr. Suzanne Parisian, (Doc. 187), Professor Wayne Ray, (Doc. 189), and Dr. James Vogel, (Doc. 191).

Throughout the country, cancer patients who have been treated with two of NPC's drugs, and who have afterwards developed osteonecrosis of the jaw, a debilitating and painful disease in which the jaw bone becomes exposed, have sued in products liability actions. In each of these cases, NPC has objected to the testimony of plaintiff's experts on varying grounds. The courts have agreed with NPC's objections to varying degrees, generally allowing the experts to testify while limiting the testimony in specific respects. This court follows the same course.

I. BACKGROUND

Aredia® and Zometa® are two FDA-approved drugs, called intravenous bisphosphonates ("BP"), manufactured by Novartis. The drugs are administered for treatment of advanced cancers which affect the bones. Plaintiff John Bartoli was treated with Aredia® and Zometa® for multiple myeloma.[1] He alleges that as a result of using the BP drugs, he developed osteonecrosis[2] of the jaw (ONJ).

This case is a pharmaceutical products liability action in which plaintiff brings claims for strict products liability, negligence, and breach of warranty. (Doc. 1). The case was transferred here from the Eastern District of New York on March 19, 2013. (Doc. 58). Before the transfer, the case was part of the Aredia® and Zometa® products liability multi-district litigation ("MDL") in the Middle District of Tennessee for pre-trial purposes. (MDL No. 1760).

Several litigation-wide experts, whose testimony is at issue here, were

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[1]Multiple myeloma is a cancer formed by malignant plasma cells. Normal plasma cells are found in the bone marrow and are an important part of the immune system. When plasma cells become cancerous and grow out of control, they can produce a tumor called a plasmacytoma. These tumors generally develop in a bone, but they are also rarely found in other tissues. When there is more than one plasma cell tumor, it is called multiple myeloma. http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma.

[2]Osteonecrosis, which is also called avascular necrosis or aseptic necrosis, is the death of bone cells due to decreased blood flow. It can lead to pain and collapse of areas of bone. http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Osteonecrosis/.

retained by the various plaintiffs whose cases were consolidated in the MDL. NPC challenged their testimony during the MDL and continues to challenge the testimony in all of the MDL cases which have been remanded for trial to various districts across the country.

II. LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which requires an expert witness to have "specialized knowledge" regarding the area of testimony. The Third Circuit has explained, "The basis of this specialized knowledge can be practical experience as well as academic training and credentials," and "[w]e have interpreted the specialized knowledge requirement liberally." Betterbox Commc'ns Ltd. v. BB Techs., Inc., 300 F.3d 325, 327-28 (3d Cir. 2002) (internal citations omitted). The Federal Rules of Evidence embody a strong preference for admitting any evidence that may assist the trier of fact. Id. Moreover, Rule 702 "has a liberal policy of admissibility." Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 806 (3d Cir.1997) .

When faced with a proffer of expert testimony, the court must determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Daubert, 509 U.S., at 592. The Daubert court held that the Federal Rules of Evidence "assign to the trial judge the task of ensuring that an expert's testimony both

rests on a reliable foundation and is relevant to the task at hand." Id., at 597. The test of reliability is "flexible," and Daubert's list of specific factors - testing, peer review, error rates, and "acceptability" in the relevant scientific community - neither necessarily nor exclusively applies to all experts or in every case. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141 (1999).

In performing its gatekeeping function to determine whether an expert's report is relevant and reliable under Daubert and Rule 702, "the court is not to weigh the evidence relied upon or determine whether it agrees with the conclusions reached therein. . . . Determinations regarding the weight to be accorded, and the sufficiency of, the evidence relied upon by the proffered expert are within the sole province of the jury." Walker v. Gordon, 46 F. App'x 691, 695 (3d Cir. 2002) (*citing* Breidor v. Sears, Roebuck & Co., 722 F.2d 1134, 1138-39 (3d Cir. 1983) ("Where there is a logical basis for an expert's opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge.")).

III. DISCUSSION

The court will address each disputed expert separately. Defendant's motions contain requests for Daubert hearings. The court finds that these issues have been litigated in case after case throughout the country, and does not believe that, with the abundance of case law addressing the specific questions at issue here, Daubert hearings are necessary. Because these

experts' qualifications have been repeatedly discussed and accepted by various courts around the country, the court will not address in depth the education, background, and experience of the various experts in question, except insofar as it is necessary to decide the motions at issue.

1. Dr. Keith Skubitz

At the MDL stage of these proceedings, Judge Campbell ruled that "the testimony of Dr. Skubitz concerning general causation and the scientific and medical accuracy of the warnings given by Novartis is clearly more than unsupported speculation," and that, "Dr. Skubitz's testimony concerning general causation and the accuracy of the warnings is admissible under Daubert." (Doc. 151). NPC's instant motion does not address testimony on those matters, but seeks to exclude Dr. Skubitz's opinions regarding: 1) alternative BP dosing; 2) pre-BP-therapy dental screening, and; 3) the incidence of ONJ in patients treated with Aredia® and Zometa®. Judge Campbell declined to rule on these specific issues in the MDL, deeming them moot because they did not apply to the summary judgment motion pending before him at the time[3]. (Doc. 151).

[3]Plaintiff has responded to defendant's motions in this case by incorporating his briefs from the MDL proceedings. These briefs cover more territory than the specific arguments defendants raise in this case, and do not specifically respond to defendant's instant arguments. While the court will consider the incorporated briefs in this case, it notes that Local Rule 7.8 specifically states that, "No brief may incorporate by reference all or any

First, as to the issue of alternative dosing schemes, NPC argues that Dr. Skubitz relies on an unreliable study to opine that less frequent dosing of the drugs in question is beneficial in preventing ONJ. Novartis objects to Dr. Skubitz's reliance on this "Corso" study because it is a retrospective observational study without a control group. The court finds that the objections as to the Corso study go more to the weight of the Dr. Skubitz's testimony than its admissibility. The litigation and documents from the MDL and related cases have recognized that if a non-controlled observational study has been peer-reviewed and accepted for publication in a scientific journal, that is a good indication that it has been "taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science." Deutsch v. Novartis Pharm. Corp., 768 F.Supp. 2d 420, 446 (E.D.N.Y. 2011). Dr. Skubitz may opine on alternative dosing as it relates to opinions based on the Corso study.

Defendant also argues that Dr. Skubitz's opinion that reduced dosing has led to decreased incidence of ONJ in his own patients is without methodological support and is prohibited *ipse dixit* testimony. The court agrees. There is nothing in Dr. Skubitz's rebuttal report, (Doc. 184-5), to suggest a scientific methodology which led him to the conclusion that alternative dosing regimens have led to a lower incidence of ONJ in his

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portion of any other brief." Moreover, the local rule also limits briefs to 15 pages, which the incorporated briefs in this matter far exceed. Plaintiff is reminded to comply with the Local Rules in any future filings with the court.

patients. Thus, this opinion is *ipse dixit*, and Daubert and Rule 702 do not permit him to offer opinions based on his observation of his own patients.

Second, defendant argues that Dr. Skubitz's opinion regarding the benefits of pre-BP-therapy dental evaluations does not satisfy Daubert's "fit" requirement, contending that there is no evidence that a warning to seek such therapy would have prevented Mr. Bartoli's jaw issues and that Mr. Bartoli had a dental examination seven months before starting BP treatment.[4] The "fit" requirement "goes primarily to relevance." Furlan v. Schindler Elevator Corp., 864 F.Supp. 2d 291, 296 (E.D. Pa. 2012)(*citing* Daubert, 509 U.S., at 591). Not knowing the exact circumstances of that visit, and without more than a glancing reference to that visit by defendants, the court cannot say that the dental visit was substantially similar to the type of pre-therapy screening Dr. Skubitz recommends, or that the visit makes the screening testimony irrelevant. As to defendant's argument that the opinion is speculative and based on retrospective research, the court refers to its above discussion of retrospective studies. Dr. Skubitz may testify as to pre-therapy dental screening.

Finally, defendant argues that Dr. Skubitz should not be allowed to testify to incidence rates of ONJ in those undergoing BP treatment. Defendant again rests this argument on the unreliability of the underlying studies on which Dr.

[4] The court notes that plaintiff has not responded to this argument.

Skubitz relies. The methodology of the underlying studies is a matter for cross-examination, but does not preclude the testimony. Deutsch, 768 F.Supp. 2d, at 431.

Accordingly, defendant's motion to exclude Dr. Skubitz's testimony, (Doc. 183), is **GRANTED IN PART AND DENIED IN PART**. Dr. Skubitz may testify as to his opinions regarding the benefits of alternative dosing, the benefits of pre-therapy dental screening, and incidence of ONJ, and defendant's motion is **DENIED** as to those topics. Dr. Skubitz may not, however, testify as to his observations regarding the incidence of ONJ after he reduced dosing in his own patients, and defendant's motion is **GRANTED** as to that issue.

2. Dr. Robert Marx

At the MDL stage of these proceedings, defendant moved to exclude Dr. Marx's testimony regarding "(1) the causal connection between Aredia and Zometa and ONJ, (2) treatment and preventative measures for ONJ, (3) alleged misconduct by NPC which he considers to be taken in "bad faith," (4) whether certain patients in the Aredia/Zometa clinical trials likely had BP-induced ONJ, and (5) criticisms of certain aspects of the clinical trials." (Doc. 154). Judge Campbell ruled that for purposes of summary judgment, Dr. Marx's testimony was admissible, with the exception of "opinions concerning the alleged "bad faith" misconduct of Novartis or his opinions concerning the

clinical trials," which Judge Campbell deemed moot, as he did not need to consider those aspects of the testimony for summary judgment purposes. (Id.).

Defendant's current motion seeks to exclude Dr. Marx from: (1) testifying that dental treatment measures prevent ONJ; (2) presenting his opinion that NPC engaged in "bad faith" conduct; (3) criticizing the clinical trials; (4) speculating that certain patients in the clinical trials for Zometa® and Aredia® had ONJ; (5) presenting general causation opinions based on adverse event reports; and (6) testifying about the biological mechanism by which BPs allegedly cause ONJ.

First, as to the biological mechanism by which BPs cause ONJ, the court finds that the MDL order already decided this exact issue, which was presented to the MDL Court.

> "However, even if the MDL court's decision was not binding, the Court would still find that Dr. Marx is more than qualified to testify with regard to this theory. Dr. Marx has conducted research, published peer-reviewed articles, and essentially served as an authority on the relationship between bisphosphonates and ONJ. The Court has no doubt that his academic involvement and extensive background in identifying, treating, and studying patients with ONJ qualifies him to render opinions on this subject."

Deutsch, 768 F.Supp. 2d, at 438-39; *see also* Doc. 154.

Second, as to general causation opinions based on adverse event reports which Dr. Marx has not reviewed, the MDL court ruled on this very issue, and it is law of the case that Dr. Marx may testify as to general causation based on adverse events reports whether he has reviewed them or

not. See id., at 450-51.

Third, as to dental treatment measures to prevent ONJ, NPC presents the same arguments as it employed in attempting to keep Dr. Skubitz from testifying on preventative dental screenings. For the same reasons as above, the court will allow Dr. Marx to opine on preventative dental screenings.

Fourth, as to whether Dr. Marx may testify as to NPC's bad faith, plaintiff argues that NPC attempted to control the conclusions of advisory boards it convened, in which Dr. Marx was personally involved, that no specialized knowledge is needed for Dr. Marx to testify about bad faith, and that he can testify to his perception of NPC's actions as they relate to how he felt NPC was dealing with him. However, "intent is not a proper subject for expert testimony" and "expert testimony that constitutes a legal opinion is inadmissible." Wolfe v. McNeil-PPC, Inc., 881 F.Supp. 2d 650, 661-62 (E.D. Pa. 2012). While Dr. Marx may testify as a fact witness about his experience working with NPC and its employees, and he may offer opinion as to what information about ONJ was available to NPC in light of the medical literature and NPC internal documents, he may not opine on whether NPC acted in good faith or otherwise opine as to NPC's intent or motivations. *See* Deutsch, 768 F.Supp. 2d, at 448.

Fifth, as to Dr. Marx's opinion that patients in the clinical trials were suffering from ONJ, NPC informed the FDA in 2005 that a retrospective review of its data from the clinical trials for the BP drugs had identified six individuals whose symptoms were "consistent with a *potential* diagnosis of ONJ." (Doc.

186). Dr. Marx, rebutting the report of NPC's expert that none of the six likely suffered from ONJ, opined that five of the six likely suffered from ONJ.(Doc. 186-3). NPC argues that Dr. Marx did not apply his own definition of ONJ in making these findings, namely, that he found the likelihood of ONJ even where the records did not reflect the presence of exposed bone, and that this lack of methodological soundness should preclude him from testifying as to this opinion.

The court agrees that Dr. Marx did not employ his own methodology, but finds that this was because the records from the clinical trials were created before there was any definition of ONJ induced by BP drugs, and so the records would not necessarily reflect the presence of exposed bone. *See* Deutsch, 768 F.Supp. 2d, at 449-50. Thus, it was reasonable for Dr. Marx to look for circumstantial evidence supporting ONJ in the incomplete records. NPC is free to cross-examine Dr. Marx about the accuracy of his opinion based on the records, but he will be allowed to give an opinion on the topic.

Finally, NPC seeks to exclude Dr. Marx's opinion criticizing NPC's clinical trials for the drugs in question. Dr. Marx states that "[a]s a research matter, I found the records to be a serious deviation of proper research data recording and noted that jaw and mouth examinations were apparently not routinely performed as part of the trial." (Doc. 186-3). NPC argues that this is inadmissible because Dr. Marx admitted that he used "20/20 hindsight," not a reliable scientific methodology, in reaching this opinion, and that Dr. Marx is

not qualified to opine on the adequacy of the trials because he had admitted that he has not "planned or managed any clinical trials" related to BP drugs, or any clinical drug trials. The court finds that Dr. Marx is not qualified to opine on the adequacy of the clinical trials. He can testify as to what information was not included in records, or that oral examinations were not performed, but he may not opine that such information or examinations should have been performed. *See* Deutsch, 768 F.Supp. 2d, at 450.

Accordingly, defendant's motion to exclude Dr. Marx's testimony, (Doc. 185), is **GRANTED IN PART AND DENIED IN PART**. Dr. Marx may testify as to preventative dental screenings, his opinion that some of the clinical trial patients had ONJ, general causation opinions based on adverse event reports, and the biological mechanism by which BPs allegedly cause ONJ. Dr. Marx may not testify as to whether NPC engaged in "bad faith" conduct, and he may not criticize the adequacy of the clinical trials.

3. Dr. Suzanne Parisian

NPC moves to exclude aspects of the testimony of Dr. Suzanne Parisian, (Doc. 187), specifically: 1) opinions regarding regulatory compliance; 2) the adequacy of the labeling of Aredia® and Zometa®; 3) any opinions regarding causation; 4) testimony regarding NPC's use of a ghostwriter, undisclosed company funding of publications, and ethical standards a reasonable pharmaceutical company should follow, and; 5) opinions about NPC's intent.

As an initial matter, Dr. Parisian has repeatedly served as a trial expert on the matters at issue here, and has significant expertise with the FDA and its practices, something about which the average layperson does not have significant knowledge. Generally, she is qualified to testify. *See* Lemons v. Novartis Pharmaceuticals Corp., 849 F.Supp. 2d 608, 613 (W.D.N.C. 2012)(collecting cases in which Dr. Parisian has been permitted to testify).

As to NPC's specific objections, first, Dr. Parisian may not testify as to NPC's intent, motive, or bad faith. As discussed above, "intent is not a proper subject for expert testimony." Wolfe, 881 F.Supp. 2d, at 661. Similarly, "bad company" opinions are not admissible. Deutsch, 768 F.Supp. 2d, at 467 (*citing* In re Trasylol Products Liability Litigation, 709 F.Supp. 2d 1323, 1337-38 (S.D. Fla. 2010)).

Second, as to pharmaceutical industry ethical standards, ghostwriting, and undisclosed company funding of publications, Dr. Parisian may not testify. There is nothing to suggest that she is an expert in pharmaceutical company ethics - she has never worked at a pharmaceutical company, and ethical standards for such companies do not come from the FDA, which is the agency about whose operations Dr. Parisian has expertise. Likewise, her testimony regarding ghostwriting and undisclosed company funding is inadmissible because she opines, without foundation, that employing such practices does not provide "fair and balanced" information and that it must be disclosed. *See* Deutsch, 768 F.Supp. 2d, at 468; *see also* Lemons, 849 F.Supp.2d, at 615.

Third, as to causation, Dr. Parisian may not testify. Dr. Parisian is not an expert in ONJ, and does not currently treat patients. Plaintiff admits as much. (Doc. 195, Ex. A, at 9). Dr. Parisian is not qualified to give causation evidence of any kind. Forman v. Novartis Pharmaceuticals Corp., 794 F.Supp. 2d 382, 384 (E.D.N.Y. 2011)(*citing* Deutsch, 768 F.Supp. 2d, at 465).

Finally, Dr. Parisian may testify as to the FDA regulatory scheme and the role of the FDA and its interactions with pharmaceutical companies. NPC objects to the methodology she employed in reaching her conclusions, and her opinions in this area have been accepted by courts again and again, and her expertise in the complicated field of pharmaceutical regulation can surely be of use to a jury. Id.(collecting cases admitting Dr. Parisian's testimony on this subject). Furthermore, the *Forman* court determined, after a two-day Daubert hearing, that Dr. Parisian's methodology for forming her opinions regarding NPC's interactions with the FDA consisted of

> "her review of certain NPC regulatory filings, internal NPC documents, and medical literature. Furthermore, as Dr. Parisian testified, she reached the opinions expressed in her report by taking this information and applying the relevant FDA regulations and procedures. As her testimony at the hearing clarified, this is the same methodology that she applied while working at the FDA."

Forman, 794 F.Supp. 2d, at 384.

The court thus determined that Dr. Parisian could testify regarding "the reasonableness of Novartis' conduct in its interactions with the FDA and compliance with FDA regulations, including Novartis' interactions with FDA

with respect to labels and warnings, and FDA regulations and interactions with companies regarding clinical trials." Id; *see also* Lemons, 849 F.Supp. 2d, at 615 (finding that Dr. Parisian's proposed testimony as to labeling is "reasoned, based on the context of the warnings, the content of the warnings, and on the consideration of the alterative language"). This court agrees, and will allow Dr. Parisian to testify on those matters.

Accordingly, defendant's motion to exclude the testimony of Dr. Suzanne Parisian, (Doc. 187), is **GRANTED IN PART AND DENIED IN PART.** Dr. Parisian may not testify as to NPC's intent, pharmaceutical industry ethical standards, ghostwriting, and undisclosed company funding of publications, or causation. Dr. Parisian may testify as to regulatory compliance and the reasonableness of NPC's conduct in its interactions with the FDA and compliance with FDA regulations, including NPC's interactions with FDA with respect to labels and warnings, and FDA regulations and interactions with companies regarding clinical trials.

4. Professor Wayne Ray

Defendant moves to exclude the testimony of Prof. Wayne Ray. (Doc. 189). Specifically, NPC seeks to exclude: 1) Prof. Ray's meta-analyses; 2) testimony that it is biologically plausible that BP drugs increase the risk of ONJ; 3) testimony that a causation opinion regarding ONJ could have been reached in 2003, and; 4) testimony regarding the incidence of ONJ in BP

patients and testimony that ONJ is not "rare."

Professor Ray is an epidemiologist, Professor of preventative medicine, director of the division of pharmacoepidemiology and director of the master of public health program at Vanderbilt University School of Medicine. He has significant experience in evaluating and designing studies to determine whether there is evidence that a medication causes bad reactions. He gives advice and does studies on adverse medication reactions and assesses whether medication use is appropriate. (Doc. 190-5).

First, NPC objects to the use of the meta-analyses employed by Prof. Ray. A meta-analysis combines the results of several studies to increase precision and reduce the likelihood that any association found by the studies is due to sampling error. Deutsch, 768 F.Supp. 2d, at 452 (*citing* Reference Manual on Scientific Evidence, Fed.Jud.Ctr. 2d ed. 2000). "Meta-analysis is best suited to pooling the results from randomly-controlled experimental studies, but if carefully performed, it is also useful for observational studies." Id. While meta-analyses can be easily misunderstood or used in circumstances where they should not be used, that does not mean they are necessarily unreliable. *See* In re Paoli R.R. Yard PCB Litig., 916 F.2d 829, 857-58 (3d Cir. 1990).

Here, Prof. Ray performed two meta-analyses. The first (the "Table 5 study") addresses the relative risk of developing ONJ while using BPs. NPC argues that Prof. Ray failed to account for some confounding factors, that he

used the patients as their own control groups, and that he treated BPs users who had been undergoing the treatment for 3 months or less as though they had not undergone BP therapy at all. However, Prof. Ray's report and his deposition testimony show that he has outlined the basis for the Table 5 study, addressed its potential flaws, and shown the methodology he employed and how he arrived at it. Moreover, he submitted a rebuttal report responding to many of NPC's complaints about his methodology. As someone with extensive experience in assessing epidemiological studies, Prof. Ray is qualified to conduct this analysis. This meta-analysis cannot be considered impermissible speculation. The court will allow Prof. Ray to testify about his Table 5 study. *See* Deutsch, 768 F.Supp. 2d, at 456-57.

Prof. Ray also performed a meta-analysis (the "Table 6 study") regarding the increased risk of developing ONJ while taking Zometa® as compared to Aredia®. NPC also objects to the reliability of the methodology of this study. Here, Prof. Ray did not employ the same reliable methodology as with the Table 5 study, failing to account for duration of therapy as it relates to increased risk, a factor which he had determined was an important one in evaluating the risk of contracting ONJ. Having concluded that duration was important, he cannot reasonably have failed to account for it in his subsequent study. Prof. Ray may not, therefore, testify as to the Table 6 study. *See* id., at 458.

Second, NPC objects to Prof. Ray's opinion that it is biologically

plausible that BP drugs increase the risk of ONJ on the grounds that he is not a medical doctor, does not prescribe BP drugs, and that he has not posited a particular biological mechanism of causation. The court disagrees. Where a "hypothesis has been deemed plausible and credible in the relevant medical literature" and where it is within an expert's "field of expertise based on training, experience, and history of publication," it is reasonable to admit that hypothesis. In re Pfizer Inc. Sec. Litig., 2010 WL 1047618, at *6 (S.D.N.Y. Mar. 22, 2010). Prof. Ray may give an opinion regarding biological plausibility.

Third, NPC objects to an opinion that a causation conclusion regarding BPs and ONJ could have been reached in 2003. NPC argues that causation has not yet been definitively proven and that the evidence Prof. Ray relies on in his analysis was not available prior to 2003. Prof. Ray bases this conclusion on Dr. Marx's report and an increase in reports of ONJ in BP users for which he does not think there is an alternate explanation. While this may not be the strongest factual basis for an opinion, that is a matter of weight, and not admissibility. Dr. Ray may testify as to whether a conclusion could have been reached in 2003.

Finally, NPC moves to exclude Prof. Ray's testimony regarding incidence of ONJ and his statement that ONJ is not "rare" in BP patients. NPC argues that Dr. Ray relied on studies that were not controlled and randomized to reach that conclusion. As the court found in the discussion of uncontrolled studies above, that is a matter of weight, and not admissibility. Dr. Ray may opine as

to incidence rate. He may not, however, testify that the incidence rate correlates to ONJ being not "rare" among BP patients. Plaintiff does not present an argument about why the term is appropriate, and the court finds that the term is undefined and could be misleading. *See* Deutsch, 768 F.Supp. 2d, at 459.

Accordingly, defendant's motion to exclude Prof. Ray, (Doc. 189), is **GRANTED IN PART AND DENIED IN PART.** Defendant's motion is **GRANTED** as to the Table 6 meta-analysis and the use of the word "rare" in relation to the incidence rate. Defendant's motion is **DENIED** as to the Table 5 meta-analysis, the biological plausibility that BPs cause ONJ, that a causation determination could have been reached in 2003, and an opinion that the incidence rate of ONJ in BP users is 5%.

5. Dr. James Vogel

At the MDL stage of these proceedings, NPC argued that Dr. Vogel was not qualified to give any of his opinions. (Doc. 152). Judge Campbell found Dr. Vogel qualified, and admitted testimony regarding "general causation and the scientific and medical accuracy of the warnings given by Novartis." (Id.). The MDL court did not consider his opinions regarding "the alleged corporate behavior of Novartis, his statement that the delay and failure in transmission of certain information impacted a large number of patients, or his testimony concerning the benefit of pretreatment dental screening." (Id.). The court thus

deemed those portions of the motion moot. (Id.).

Presently, defendant moves to exclude the testimony of Dr. James Vogel. (Doc. 191). Specifically, defendant wished to exclude opinions regarding: 1) NPC's corporate conduct; 2) pre-BP treatment dental screenings; 3) incidence of ONJ; 4) alternative BP dosing regimens, and; 5) biological mechanism by which BPs affect jaw bones.

Dr. Vogel has been a hematologist and medical oncologist for 35 years. He sees patients regularly, and sees patients with both "solid tumors," as well as blood cancers such as multiple myeloma. He is as Associate Professor of hematology and medical oncology at the Mount Sinai School of Medicine. He prescribes BP drugs to his patients.

First, as to testimony about NPC's corporate conduct, NPC argues that Dr. Vogel lacks any firsthand knowledge and formed his opinions from internal NPC documents presented to him during litigation. They allege that Dr. Vogel cannot testify:

> (1) that NPC misrepresented causation evidence; (2) that NPC referenced corticosteroids as potential risk factors for ONJ in the warnings on its label to misdirect "the focus of medical attention away from the jaw area"; (3) that NPC minimized the incidence rate of ONJ; (4) that ONJ occurs in a patient after fewer infusions of Zometa® than of Aredia® and/or that NPC knew and failed to communicate that information; and (5) that a decrease in the duration and/or dosing frequency of therapy decreases the incidence of ONJ or that NPC knew and failed to communicate that information.

As noted above, an expert may not opine as to the intent or motive of NPC. To

the extent that Dr. Vogel's testimony seeks to do this, it will not be allowed. However,

> "Dr. Vogel can opine on the medicine and science that was available at the time regarding the risks and benefits of Aredia and Zometa, and can compare that information to what was disclosed on the label or in other materials Novartis presented to the medical community. To the extent the information on the known risks is derived from internal Novartis documents, Dr. Vogel's scientific expertise is helpful to the trier of fact in understanding those documents."

Deutsch, 768 F.Supp. 2d, at 443.

Second, in accordance with the court's above rulings regarding the testimony of Dr. Marx and Dr. Skubitz on the same topic, Dr. Vogel will be permitted to testify as to the benefits of pre-treatment dental screenings.

Third, as to opinions regarding the incidence rate of ONJ in BP patients, the court has addressed this issue in discussing Dr. Skubitz and Dr. Marx. For the same reasons, the court finds that NPC's objections regarding the reliability of the underlying studies and Dr. Vogel's failure to consider studies published after his initial report go to the weight of the evidence, not to its admissibility. Dr. Vogel may testify as to incidence rate of ONJ in BP patients.

Fourth, NPC objects to Dr. Vogel's opinions regarding an alternative dosing schedule because he relies on the same Corso report as Dr. Marx, and he lacks expertise regarding FDA labeling. First, the court noted above that reliance on the Corso study is permissible. As to whether he is qualified to opine on the dosing information that NPC should have provided to the medical

community, the MDL court ruled that Dr. Vogel may testify as to whether the label dosing information was false or misleading. Thus, Dr. Vogel may testify as to alternative BP dosing regimens.

Finally, as to whether Dr. Vogel may opine about the biological mechanism by which BPs affect jawbones, NPC contends that Dr. Vogel is not qualified to opine because he is not a bone pathologist or bone biologist. "While the MDL court did find that Dr. Vogel's inability to explain the mechanism did not render his opinions unreliable as to the biological mechanism generally, the MDL court did not directly address whether Dr. Vogel is qualified to offer an opinion on the particular hypothesis about bisphosphonates targeting the bone." Id., at 439. This court finds that Dr. Vogel is qualified to testify on the matter. While he admits that he is not an expert in bone pathology, he is an expert in cancers of the blood, a closely related field at the heart of this case. "Rule 702's liberal policy of admissibility extends to the substantive as well as the formal qualification of experts. We have eschewed imposing overly rigorous requirements of expertise and have been satisfied with more generalized qualifications." Paoli, 35 F.3d, at 741. Furthermore, Dr. Vogel is not offering his opinion as the mechanism, but rather indicating that it is a plausible one given his understanding of the relevant medical literature. Deutsch, 768 F.Supp. 2d, at 439. Dr. Vogel may testify as to the biological mechanism.

Accordingly, defendant's motion to exclude the testimony of Dr. Vogel,

(Doc. 191), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** to the extent that Dr. Vogel may not opine as to the intent or motive of NPC. Defendant's motion is **DENIED** as to testimony regarding pre-dental screenings, incidence rate of ONJ in patients, alternative BP dosing regimens, and the biological mechanism by which BPs affect the jaw bone.

IV. CONCLUSION

For the foregoing reasons, each of defendant's motions, (Doc. 183, Doc. 185, Doc. 187, Doc. 189, Doc. 191), is **GRANTED IN PART AND DENIED IN PART**. A separate order shall issue.

s/ *Malachy E. Mannion*
MALACHY E. MANNION
United States District Judge

Date: April 17, 2014

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